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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,089

08/26/2003

Samuel H. Gellman

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08/19/2008

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EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

08/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,089	Applicant(s) GELLMAN ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6,8,9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments/Amendments

Applicant's amendments and arguments filed April 4, 2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 4, 6, 8, 9 and 11 are pending.

Claims 8, 9 and 11 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Upon further consideration, the 35 USC § 112, 1st ¶ (written description), rejection based upon the lack of representative number of examples is withdrawn. The claims recite no functional language, and thus the claims provide description for unnatural polypeptides as currently claimed.

With regards to the rejection under 35 USC § 101 and 112, 1st ¶ (enablement), Applicant argues three points with Schmitt- 1) it is not contemporaneous with the filing of the instant application, 2) did no testing of the compounds therein and 3) they *hypothesized* a general utility. Applicant argues the reliance upon Schmitt in making the argument of lack of utility is improper asserting that the compounds are non-analogous and were not tested for utility.

Applicant states that the Office has indicated the utility cited by Dr. Gellman in the previously provide 132 Declaration was 'likely' sufficient for purposes of 112 1st paragraph, and provides an abstract from Petros (2004) showing the "utility was clearly well established in the

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art”. Applicant further argues that Kim, while contemporaneous, is not analogous because it has different utility with different compounds.

Respectfully, the examiner disagrees. Applicant appears to misinterpret the examiner’s previous position regarding the Declaration of Dr. Gellman. As discussed previously, Dr. Gellman’s declaration *would have possibly* provided enablement had the instant specification provided explicit direction to the selection Bcl-x_L/BH3 interaction and the specific probe that was used in the declaration. This was not a statement that utility was found in the instant Application, as there is no mention of such specific interaction found in the specification, and only finds support in the declaration. Given the infinite number of compounds embraced by the claims, the specification lacks any guidance as to how one would have selected the specific compounds used. Similarly, given the infinite number of protein-protein interactions, nothing in the specification provides guidance as to how one would have known to pick Bcl-x_L/BH3 and to use the specific compounds tested. Further, with regards to Petros, it was published after the instant Application and cannot be relied upon to show the asserted utility provided in the declaration was known at the time of filing. Again, nothing in the specification would lead one to look to Bcl from the infinite number of proteins, given the absence of any disclosure of any single protein in the specification-particularly the absence of any mention of Bcl. Similarly, in *In re Fisher*, 76 USPQ2d 1225 (Fed. Cir. 2005), the court stated, “Here, granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher's

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claimed ESTs may add a noteworthy contribution to biotechnology research, our precedent dictates that the '643 application does not meet the utility requirement of §101 because Fisher does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.” While *Fisher* is drawn to utility/enablement of ESTs, the fact pattern remains substantially similar. The instant compounds and the compounds in *Fisher* both have general, not specific, utility where the specific utility is nebulously defined such that further research is required to determine what is the practical utility.

With regards to Kim, the examiner has provided this reference to show that other compounds hypothesized to do what is instantly claimed failed to do so. The examiner acknowledges that Kim is different that the asserted utility provided by Dr. Gellman in the declaration, however it is within the asserted general utility of the disclosure. Regardless of the difference in structure, it clearly provides evidence that the art is highly unpredictable with regards to probing protein-protein interaction when the target is known and the ligand is a mimetic of something that is known to bind. They could not make a ligand probe for a known interaction, and thus could not study 'protein protein interactions', thus clearly casting doubt as to how one would develop a probe for a nebulous interaction when the interaction to be studied is not defined, nor are the proteins being studied.

With regards to Schmitt, the examiner agrees with many of Applicant's statements- it hypothesizes interaction, did not test any compounds and is not contemporaneous. However, the examiner see this teachings as supporting the lack of enablement and utility. After the filing date

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of Applicant, again, another person merely hypothesizes that it may be possible, not that it is possible- or had been done. The level of skill and knowledge is clearly low, as it is evident that both prior to, and post (Kim and Schmitt, respectively), it had not been done and remained a mere hypothetical possibility.

Claim Rejections - 35 USC §§ 101 and 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 6 are/remain rejected under 35 U.S.C. § 101, for the reasons of record and those set forth below, because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Claims 4 and 6 are/remain rejected under 35 U.S.C. § 112, first paragraph (enablement), for the reasons of record. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth under 35 USC § 101, one skilled in the art clearly would not know how to use the claimed invention.

KIM (Y.J. Kim et al. Bioorg. Med. Chem. Let. (2000) 10, pages 2417-2419) teaches β Pro₁₀-Tyr, (previously relied upon under 35 USC § 102). Kim examined “the possibility that β -peptide can substitute for the natural peptide” (page 2418) as a ligand of profilin and that it “failed to bind profilin, whereas the corresponding α -L-proline decamer bound tightly to this protein” (Abstract). Here, Kim provides the possibility of studying the interactions, but

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determines *inter alia* that the probe is unsuitable, and thus it is inoperative. Without a probe, one cannot study the binding between two proteins.

With regards to Seebach, the Examiner considered the disclosure of Seebach to be inapplicable, as the compounds of Seebach are γ -dipeptides, while the instantly claimed compounds are, at minimum, tetrapeptides with at least 1 α -amino acid and at least 2 cyclically constrained β -amino acids. The compounds are not coextensive or commensurate in scope, and thus cannot provide a 'well established utility' for the instant compounds based upon structure and amino acid content. Furthermore, Seebach merely provides further evidence that the compounds are not of a well established utility, as even Seebach states that the results, "promise a potential of γ -peptides for the development of peptidase-resistant peptidomimetic drugs." (page 777, last paragraph). Seebach makes no reference or inference that the compounds relate to tetrapeptides (or larger) with α and cyclically constrained β -amino acids that are instantly claimed.

More recently, SCHMITT (M.A. Schmitt, et al. J. Am. Chem. Soc. (2005) 127, pages 13130-13131) teaches compounds which are of a similar structure to those of the instant application (e.g. compound 1). Schmitt, while not contemporaneous with the instant application, provides that the art still does not provide a 'well established' utility, as Schmitt teaches that, "Foldamers of this type [α/β -peptides] might mimic recognition surfaces on proteins and thereby disrupt specific protein-protein interactions [citing Sadowsky (2005)] or perform multifunctional catalysis of chemical reactions." (page 13131, last paragraph). These are general utilities, not specific as required by the statute.

Disruption of protein-protein interactions is a generic utility, and the questions that arise are, “which specific protein-protein interactions are contemplated and disclosed to be disrupted by Applicant?” and, “to what end are the interactions disrupted (e.g. increasing clot formation, preventing angiogenesis, increasing milk production, etc.)?” The specification is silent to any specific protein-protein interaction that is disrupted or what is the effect of the disruption.

While chemical libraries are commercially available, they are sold as research tools, which are clearly delineated by MPEP § 2107.01(I) as being a utility which is not substantial (*see, e.g. page 7, Office Action mailed 5/4/05*). It is noted that the Exhibits previously presented do not discuss the particulars of the instant invention, e.g. examples of the instantly claimed compound, but rather generalizations on peptide libraries. Furthermore, as stated in the previous office action the MPEP states, “An assessment that focuses on whether the invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.” (Emphasis added; *see page 7, Office Action mailed 5/4/05*).

Furthermore, MPEP § 2107 (II)A(3) (the Examination Guidelines for the Utility Requirement) sets forth the test for determining a ‘well established utility’, stating, “If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or

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applications of a product or process), and (ii) the utility is specific, substantial, and credible.” (emphasis added). A ‘well-established’ utility requires that the utility is specific, substantial and credible, and not a ‘general’ utility, as is the case in the instant application because there is no specifically identified substantial utility and the invention requires further research and testing to determine what specific protein-protein interactions may be disrupted with the compounds of the instant invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 8, 9 and 11 drawn to an invention nonelected with traverse in the reply filed on March 7, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654